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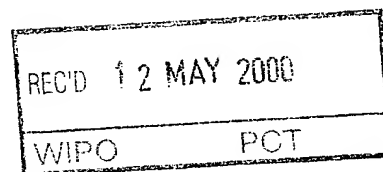
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*new*

# Kongeriget Danmark

Patent application No.: PA 1999 00464  
Date of filing: 07 April 1999  
Applicant: Coloplast A/S  
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The attached document is a true copy of the following document:

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28 April 2000

  
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**TITLE**

A dressing

**FIELD OF THE INVENTION**

The present invention relates to a dressing used for prophylaxis or treatment of  
5 ulcers, the use of the dressing and a method of indicating that a body part has  
been exposed to a critical pressure level.

**BACKGROUND OF THE INVENTION**

Many people, especially diabetics, who suffers from long term complications such  
as ischeamia and neuropathy or patients confined to their bed are known to  
10 develop ulcers on foot, hip or sacrum. Foot ulcers are usually located on the  
plantar or on the side or dorsum of the foot. Foot ulcers are induced by changes  
in bone structure, which can lead to protruding prominences and reduced thick-  
ness of the subcutaneous layer that ensures the distribution of the pressure  
applied to the foot.

15 The development of foot ulcers are i.e. dependent on a combination of etiology  
and the induction of pressure. There are essentially two mechanical inducers for  
pressure sore development, the stress of permanent (static) pressure and the  
stress of short term (dynamic) pressure.

The permanent or static pressure is when exertion of pressure over a long period  
20 (hours typically) is leading to the risk of collapse of veins and arteries. The  
collapse of these blood vessels may lead to ischemia e.g. lack of oxygen and  
nutrition and a build up of waste materials. These events may eventually lead to  
development of ulcers. The tendency is the longer period of pressure induction,  
the lower pressure is critical and may cause damage.

25 Short term or dynamic pressure impact is in the form of repetitive mechanical  
stress. This occurs e.g. when walking, where typical a pre-stage to ulceration is  
callus build-up. This type of ulceration may be compared to benign sanguinous

blister formation. Critical pressure level of this type of pressure impact is much higher than in the case of a long time pressure load. However, the critical pressure level is still lower on e.g. diabetic feet compared to normal healthy feet.

- Diabetic patients are often suffering from neuropathy, rendering their sensibility skills to be greatly diminished or they may even suffer from a complete loss of feelings in the lower extremities, and especially in the feet. The patient will often fail to notice or be aware when individual points of a foot are subjected to severe constant pressure or repetitive stress, for example during long periods of standing, inducing the development of an pressure sore. Since metabolism and blood circulation already are reduced in diabetes patients, healing of such sores is most difficult.

Attempts have been made to prevent the development of pressure sores and ulcers in a patient who might not be able to recognise presence of severe sore inducing condition.

- Dressings with different kinds of indicators are known, e.g. from European Patent application No. 430 680 (E. R. Squibb & Sons, Inc. ), which discloses a wound dressing comprising a temperature sensing liquid crystal tape, affixed to the backing layer. A temperature change may indicate a change in wound condition. In the reference is also mentioned the possibility of a pressure indicator in the form of a piezoelectric element.

- US Patent No. 5 642 096 (Paromed Medizintechnik GmbH) discloses a device for prevention of ulcers on the feet of diabetic patients. The device includes a pressure and temperature sensor in the form of a piezoelectric element carried in the innersole of the shoe. The patient is warned by a signal, e.g. a buzz if the pressure reaches a critical level. The device is constricted to the innersole of the shoe, and does not cope with detecting impacts to other body parts e.g. the side of the foot or on hips or sacrum, and it is also technically complicated and expensive.

Accordingly, it is desirable that there be provided a simple device being capable of indicating that an adverse pressure has affected a body part, especially the feet, of a patient, in an easily detectable manner.

#### **BRIEF DESCRIPTION OF THE INVENTION**

- 5 The present invention relates to a dressing.

The invention also relates to the use of a dressing.

The invention further relates to a method of indicating that a body part has been exposed to a critical pressure level.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

- 10 The invention is explained more in detail with reference to the drawings in which:  
Figure 1 shows a top view of an embodiment of the invention.  
Figure 2 shows a cross-section of an embodiment of the invention.  
Figure 3 shows a cross-section of another embodiment of the invention.  
Figure 4 shows a further embodiment of the invention seen from above.  
15 Figure 5 shows a cross-section of the embodiment of Figure 4.  
Figure 6 shows a cross-section of yet another embodiment of the invention.  
Figure 7 shows a cross-section of a still further embodiment of the invention.

#### **DETAILED DESCRIPTION OF THE INVENTION**

- The invention relates to a dressing comprising a pressure indicator being visible  
20 from the distal side of the dressing, when in use, said pressure indicator showing a durable change after having been exposed to a pressure above a defined level.

The dressing according to the invention offers a simple solution to the above mentioned problem.

The indicator may be dispersed in an adhesive.

In one embodiment of the invention the indicator is incorporated in a film.

The indicator is preferably capable of producing a colour change. Alternatively, the indicator may create a visible change by changing solubility, and in this way change form e.g. clear to opaque.

- 5 In another embodiment of the invention the indicator may be in the form of a pressure indicating film, preferably in the form of a mono- or bilayer film.

The indicator may be in the form of microcapsules. These microcapsules may be coated on the dressing or a film or they may be homogeneously dispersed as discrete particles in a matrix, such as an adhesive, absorbent or pressure distrib-  
10 uting element.

The incorporation of a pressure indicator renders it possible for the patient or the health care person, to monitor the points of critical pressure in the area around the wound without removing the dressing.

The pressure indicator may be provided in a form either having gradual pressure  
15 indication properties or the indicator may have a critical pressure level, above which the indicator will develop a visual indication.

In a preferred embodiment of the invention the dressing comprises an absorbing element and a pressure distributing element, the absorbent element constitutes a part of a proximal skin contacting surface, said absorbing element being encircled  
20 by the pressure distributing element constituting the remaining part of the surface of the dressing to be in contact with the skin.

The combination of an absorbing part combined with an elastomer ensures, that no changes in properties due to long term pressure is observed. The combination

of the materials into one, very flexible, thin device ensures that shoes can be worn when using the device.

In order to prevent the development of ulcers and/or enhance the healing of ulcers a combination of an absorbing element and a pressure distributing and  
5 pressure shock-absorbing element has been shown to be advantageous. The absorbing element will be able to handle exudates from a wound and provide the optimal environment for wound healing, while the pressure distributing element will work as a shock absorber and a pressure distributing element and diminish further damage to the wound area.

10 The dressing according to the present invention reduces the impacts from pressure shocks to the selected body part, and offers pressure distributing properties of susceptible areas. These properties are important both in the prophylactic phase as well as in the treatment of an ulcer. The absorbing element of the dressing of the invention is preferably more compressible than the pressure  
15 distributing element covering the area next to the treated areas and in that way reducing the direct pressure on the wound.

The combination of an absorbing element combined with an pressure distributing element ensures that no changes in properties of the dressing due to long term pressure is observed. The dressing of the invention can be in the form of a very  
20 flexible, thin device of a size rendering it suitable for wearing in shoes without discomfort.

In one embodiment of the invention the dressing may be substantially planar with circular or elliptical shape for use on e.g. heels.

In another embodiment of the invention the dressing may be in the form of a  
25 three-dimensional structure e.g. for use on toes.

The indicator may be incorporated in the pressure distributing element.



The pressure distributing element is preferably an elastomer.

The pressure distributing element may preferably comprise synthetic polymers such as silicones, polyurethanes, elastomeric copolymers or hydrophobic foams with designed properties or it may be a natural polymer such as natural rubbers.

- 5 The elastomer has great ability of distributing both the static pressure and the sudden impacts, and at the same time it is durable and does not collapse during use, but conserves its elasticity and shape.

In a preferred embodiment of the invention a water permeable elastomer is used, enabling water vapour transport through the dressing.

- 10 The product can be used both as an ulcer prophylaxis and as a wound dressing for all kinds of pressure ulcers, such as foot ulcers, leg ulcers, hip ulcers and sacrum ulcers.

The absorbent element may comprise a hydrophilic foam, such as polyurethane, silicone, styrene-butadiene, styrene-isoprene or a surface coated polyethylene, or

- 15 a water soluble or gelling biopolymers such as polysaccharides, e.g. alginates, polyvinyl-pyrrolidone gels or hydrocolloids.

Preferably the absorbent element is more compressible than the pressure distributing element.

- 20 The absorbent element may be located as discrete or connected zones in the pressure distributing element, either penetrating the pressure distributing element from top side to the skin-contacting side of the element or only going partly through the dressing, with the open end towards the skin.

The zones of the absorbent element may be of any shape, e.g. in the form of dots, lines, squares or concentric circles.

In an embodiment of the invention the absorbent element may comprise more than one absorber, e.g. a foam part in the portion in contact with the skin, and on top of the foam a super absorber part being capable of soaking the moisture from the foam and in this way remove excess moisture from the skin-contacting part.

- 5 The device can be wholly or partly covered with an adhesive on the skin-facing surface to fix the device to the wearers body-part, e.g. the heel. Alternatively, the adhesive can be located on the non-skin facing side, and in this way attach the device to the innersole of wearers shoe.

In one embodiment the pressure distributing element has adhesive properties.

- 10 The device may be covered on the non-skin-contacting surface with a top layer, e.g. a foam, a non-woven or a film such as a polyurethane film. The layer will enhance the strength of the dressing as well as it may serve as a barrier for the wound exudate.

- In one embodiment of the invention the top layer extends beyond the edge of the  
15 pressure distributing element defining a flange around the dressing. The flange may optionally be covered with an adhesive.

- A protective cover or release liner may for instance be siliconised paper. It does not need to have the same contour as the dressing, e.g. a number of dressings may be attached to a larger sheet of protective cover. The protective cover is not  
20 present during the use of the dressing of the invention and is therefore not an essential part of the invention.

Furthermore, the dressing of the invention may comprise a "non touch" grip known per se for applying the dressing to the skin without touching the adhesive layer. Such a non-touch grip is not present after application of the dressing.

The dressing according to the invention may comprise wound healing associated indicator(s) such as indicators of pH, partial pressure of O<sub>2</sub>, temperature, radical mechanisms or biotechnological assays, e.g. indicating formation of collagen.

- It is also advantageous that a dressing according to the invention comprises
- 5 wound healing associated indicator(s), cushions or similar device for treatment or prophylaxis of formation of wounds and/or skin abnormalities.

- This opens for a combined medical treatment of the wound and an easy and sterile application of the active ingredients, e.g. by incorporating active ingredients such as a cytokine such as growth hormone or a polypeptide growth factor
- 10 giving rise to the incorporation of such active substances in a form being apt to local application in a wound in which the medicament may exercise its effect on the wound, other medicaments such as bacteriostatic or bactericidal compounds, e.g. iodine, iodopovidone complexes, chloramine, chlorohexidine, silver salts such as sulphadiazine, silver nitrate, silver acetate, silver lactate, silver sulphate,
- 15 silver-sodium-thiosulphate or silver chloride, zinc or salts thereof, metronidazol, sulpha drugs, and penicillins, tissue-healing enhancing agents, e.g. RGD tripeptides and the like, proteins, amino acids such as taurine, vitamins such as ascorbic acid, enzymes for cleansing of wounds, e.g. pepsin, trypsin and the like, proteinase inhibitors or metalloproteinase inhibitors such as Illostat or ethylene
- 20 diamine tetraacetic acid, cytotoxic agents and proliferation inhibitors for use in for example surgical insertion of the product in cancer tissue and/or other therapeutic agents which optionally may be used for topical application, pain relieving agents such as lidocaine or chinchocaine, emollients, retinoids or agents having a cooling effect which is also considered an aspect of the invention.
- 25 The invention also relates to the use of a dressing comprising a pressure indicator being visible from the distal side of the dressing, when in use for indicating a critical pressure impact to a body part.

The invention relates further to a method of indicating a critical pressure level to a body part, comprising applying a dressing comprising a pressure indicator being visible from the distal side of the dressing, when in use, and after a period of use, inspecting the dressing and detecting an indication of critical pressure.

## 5 DETAILED DESCRIPTION OF THE DRAWINGS

A preferred embodiment of the invention is shown in Figure 1. In this embodiment, a zone of absorbing material (1) surrounded by a pressure distributing material (2). The indicator (8) is homogeneously dispersed in the pressure distributing material.

- 10 In Figure 2 is shown a cross-section of an embodiment of the invention, with a zone of absorbent element (1) and a pressure distributing element (2). On the distal side of the absorbing element is a pressure indicating film (9). The edges of the dressing are bevelled or rounded to enhance the comfort for the user.

- In Figure 3 is shown another embodiment of the invention in which the surface of  
15 the dressing not contacted with the skin is covered by a top layer (3). The top layer (3) may enhance the mechanical strength of the dressing. The top layer may be a pressure indicating film.

- Figure 4 shows another embodiment of the invention seen from above. The absorbent element (1) is distributed as discrete zones in the pressure distributing  
20 element (2). The indicator may be homogeneously dispersed as discrete particles in either elements, or the dressing may be covered partly or wholly with a pressure indicating film.

- In Figure 5 is shown a cross-section of the same embodiment of the invention with one absorbing element (1) at the skin-contacting surface, and on top of the  
25 absorbing element is a super absorber (4). A top layer (3) is covering the non-skin-facing surface of the dressing. The top layer may comprise a pressure indicator.

In Figure 6 is shown another embodiment of the invention in which the edges are not bevelled, with a top layer (3) on one side and a layer of a an adhesive (5) on the skin-facing side. The indicator is homogeneously dispersed as discrete particles in the adhesive.

- 5 Figure 7 is showing an embodiment of the invention in which the top layer (3) is elongated to extend beyond the pressure distributing element (2). On the elongated part of the layer (6) an adhesive (7) is applied, essentially making the concept an island dressing, with an adhesive flange and a non-adhesive centre part. The indicator may be incorporated in the top layer, pressure distributing  
10 element or absorbing element.

**CLAIMS**

1. A dressing comprising a pressure indicator being visible from the distal side of the dressing, when in use, said pressure indicator showing a durable change after having been exposed to a pressure above a defined level.
- 5 2. A dressing according to claim 1, characterised in that the indicator is capable of producing a colour.
3. A dressing according to claim 1 or 2, characterised in that the indicator comprises a pressure indicating film, preferably in the form of a mono- or bilayer film.
- 10 4. A dressing according to any of claims 1-3, characterised in that the indicator is in the form of microcapsules.
5. A dressing according to any of claims 1-4, characterised in that the surface opposite the skin-contacting surface of the dressing is covered by a layer.
6. A dressing according to any of claims 1-5 characterised in that the dressing  
15 comprises an absorbing element and a pressure distributing element, the absorbent element constitutes a part of a proximal skin contacting surface, said absorbing element being encircled by the pressure distributing element constituting the remaining part of the surface of the dressing to be in contact with the skin.
7. A dressing according to claim 6, characterised in that the pressure distributing  
20 element is an elastomer.
8. A dressing according to any of claims 6 or 7, characterised in that the absorbent element comprises a hydrophilic foam, such as polyurethane, silicone, styrene-butadiene, styrene-isoprene or a surface coated polyethylene, or a water soluble or gelling biopolymers such as polysaccharides, e.g. alginates, polyvinyl-  
25 pyrrolidone gels or hydrocolloids.

9. A dressing according to any of claims 1-8, characterised in that the absorbent element comprises a pharmaceutical or antimicrobial agent.

10. Method of indicating a critical pressure level to a body part, comprising applying a dressing comprising a pressure indicator being visible from the distal side of  
5 the dressing, when in use, and after a period of use, inspecting the dressing and detecting an indication of critical pressure.

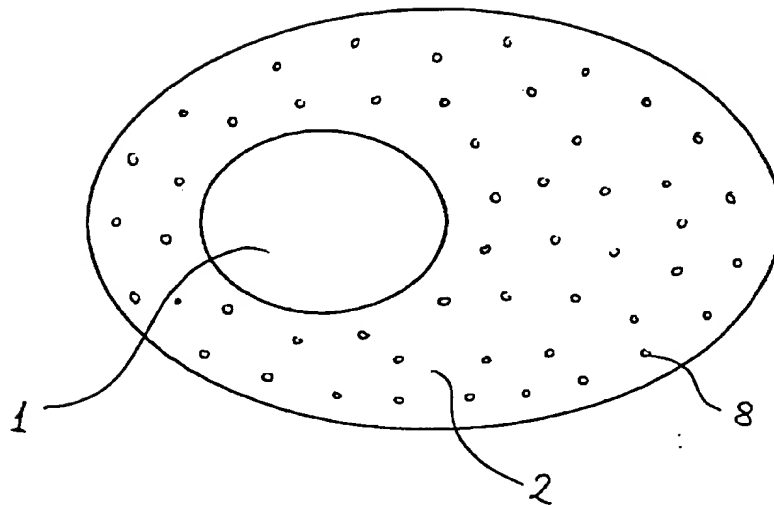
**ABSTRACT**

**A dressing**

A dressing comprising a pressure indicator being visible from the distal side of the dressing, when in use, said pressure indicator showing a durable change after  
5 having been exposed to a pressure above a defined level may indicate that a body part has been affected by an adverse pressure.

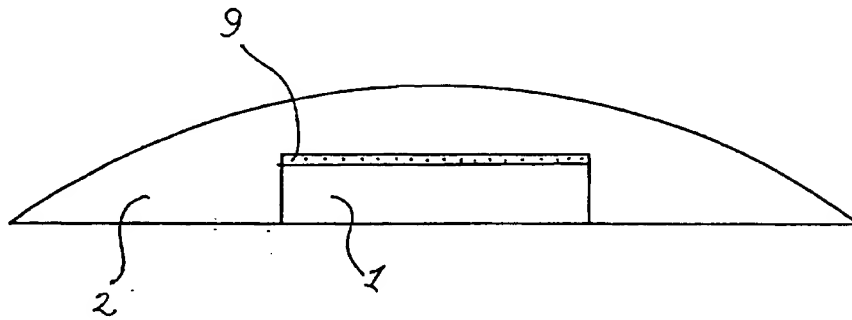


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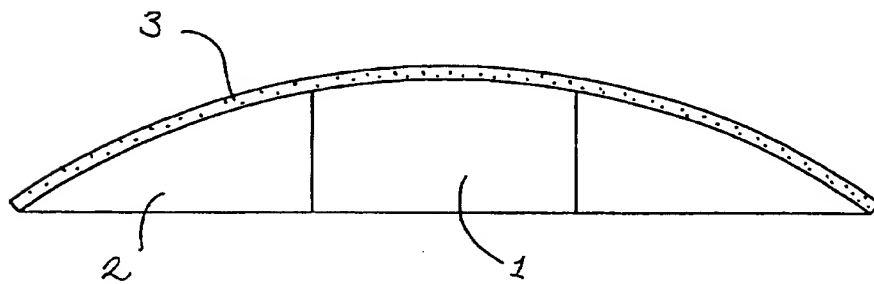


*Fig. 1*

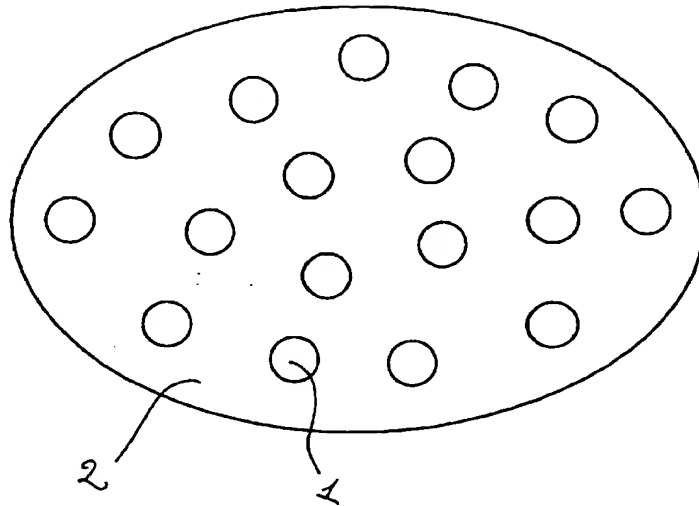
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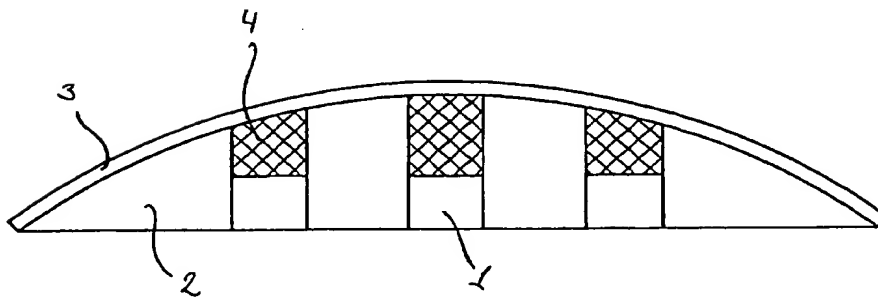
*Fig. 2*



*Fig. 3*



*Fig. 4*



*Fig. 5*

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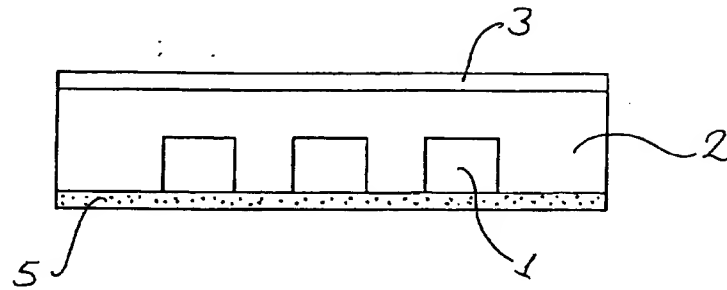


Fig. 6

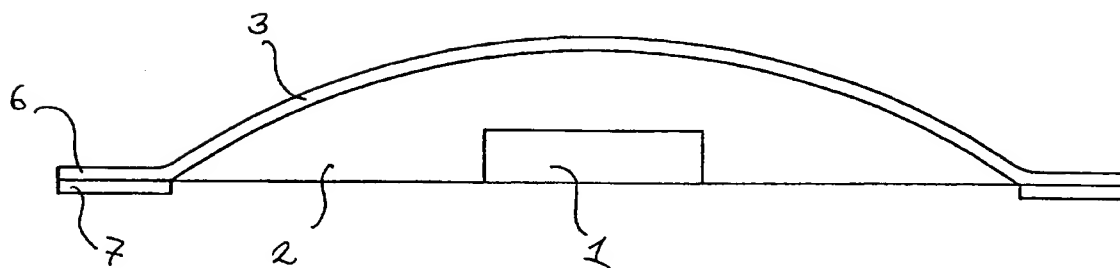


Fig. 7